

For Attention of: [REDACTED]

Subject:

Call back of Sterile single use devices (TRANBERG® | Laser Applicator, TRANBERG® | Introducer / TRANBERG® | Tissue Temp Probe) for the TRANBERG® Thermal Therapy System

At CLS, our commitment is to never compromise on safety compliance or quality of our products and services.

March 31, 2021, SterilMilano, the service provider of sterilization of CLS 'sterile single use devices, informed us that they cannot guarantee that the validation of the sterilization process of our products has been properly conducted (validation performed 2014 and revalidation performed 2018). They have found traces of fraud in several stages of the operations and cannot define the extension and impact of these events.

Based on this information, CLS concludes there is a potential risk that delivered products do not fulfill the defined sterility assurance level (SAL of 10^{-6}) and should therefore not be used in treatments any longer.

We have therefor decided to call back products that have been distributed to our cooperation partners and customers.

As of now these products are on hold at CLS own stock. We consider that there is no risk for patient harm from already used products.

Actions

Delivered TRANBERG® | single use products shall not be used. Please confirm upon receive of this letter that you have taken part of this field safety notice by emailing the filled in reply (appendix 1) to lotta.ljungberg@clinicallaser.com.

According to our documentation we have shipped concerned products as listed below to you.

We request you to collect all concerned products remaining in your stock and return these at your earliest convenience to CLS, but not later than April 30, 2021, attention

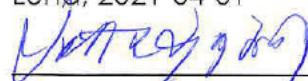
to Lotta Ljungberg, (the address is found in the bottom of this letter). All costs for this collection and return of products will be taken by us.

Please inform us how many products you will return latest 2021-04-15. Fill in the later part of appendix 1 when you have identified number of remaining products at your site.

Thanks for your cooperation!

Please do not hesitate to contact us for further questions.

Lund, 2021-04-01



Lotta Ljungberg, VP of QA/RA

Mobile [REDACTED]

lotta.ljungberg@clinicallaser.com

Shipped products

Product Name	Article no.	Batch ID	No. of pcs
Tranberg Laser Applicator non-cooled (diffuser)	4017-01	00017/2019/01	25
Tranberg Laser Applicator non-cooled	4012-05	00162/2018/08	15
Tranberg Laser Applicator non-cooled (diffuser)	4017-04	00177/2018/10-2	15
Tranberg Standard Introducer 10 cm	4013-01	AS20180305	30
Tranberg Standard Introducer 20 cm	4013-02	AS20180306	10
Tranberg Tissue Temperature Probe	3201-01	AS202000046	16
Tranberg Tissue Temperature Probe	3202-01	AS202000047	13
Tranberg Laser Applicator non-cooled (radial)	4012-01	00135/2020/06	5
Tranberg Laser Applicator Non-cooled (diffuser)	4017-02	00090/2020/04	5
Tranberg MR Catheter, L230 mm	4013-10	AS202000142	5
Tranberg MR Stylet, L100 mm	4013-11	AS202000143	5
Tranberg MR Catheter, L100 mm	4013-12	AS202000144	5

Clinical Laserthermia Systems AB

Scheelevägen 2
SE-223 81 Lund, Sweden
VAT: SE556705890301
Phone: +46 (0) 46 15 21 00
www.clinicallaser.se

Appendix 1 Reply Form

Please confirm that you have taken part of this field safety notice, sign and return to lotta.ljungberg@clinicallaser.com latest April 6, 2021

I hereby confirm that I have read and understood the field safety notice 2021-1 and understand the actions need to be taken to discontinue the use of the Tranberg sterile single use products as listed in the field safety notice and to return products to CLS.

.....
Name/Signature/Title

Company name.....

Contact information (email, mobile).....

Please fill in the number of products to be returned and send your reply to lotta.ljungberg@clinicallaser.com not later than April 15, 2021. We will come back with details how to return the products.

Product Name	Article no.	Batch ID	No. of pcs.	Remaining pcs. at customer's stock
Tranberg Laser Applicator non-cooled (diffuser)	4017-01	00017/2019/01	25	
Tranberg Laser Applicator non-cooled	4012-05	00162/2018/08	15	
Tranberg Laser Applicator non-cooled (diffuser)	4017-04	00177/2018/10-2	15	
Tranberg Standard Introducer 10 cm	4013-01	AS20180305	30	
Tranberg Standard Introducer 20 cm	4013-02	AS20180306	10	
Tranberg Tissue Temperature Probe	3201-01	AS202000046	16	
Tranberg Tissue Temperature Probe	3202-01	AS202000047	13	
Tranberg Laser Applicator non-cooled (radial)	4012-01	00135/2020/06	5	
Tranberg Laser Applicator Non-cooled (diffuser)	4017-02	00090/2020/04	5	
Tranberg MR Catheter, L230 mm	4013-10	AS202000142	5	
Tranberg MR Stylet, L100 mm	4013-11	AS202000143	5	
Tranberg MR Catheter, L100 mm	4013-12	AS202000144	5	